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 Sanofi-Aventis, U.S., Inc., and  
 Sanofi-Synthelabo, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
 FOR THE DISTRICT OF ARIZONA**

BEATRICE MILLS,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY,  
 SANOFI-AVENTIS U.S., L.L.C.,  
 SANOFI-AVENTIS, U.S., INC., and  
 SANOFI-SYNTHELABO, INC.,

Defendants.

Case No. CV-11-968-PHX-FJM

**DEFENDANTS' REPLY  
 IN SUPPORT OF THEIR MOTION  
 TO DISMISS PURSUANT  
 TO FEDERAL RULES  
 12(b), 8(a), AND 9(b)**

Plaintiff's opposition fails to address the fundamental deficiencies in Plaintiff's Complaint: its failure to connect the few facts alleged to *this* Plaintiff and its failure to plead essential elements of Plaintiff's claims. Instead, Plaintiff argues that *Twombly* and *Iqbal* did not change the pleading standard and do not apply here. The Ninth Circuit, though, has expressly stated that the new pleading standard is a significant change in the law that applies to every civil action filed in federal court. Plaintiff's Complaint accordingly should be dismissed.

**I. PLAINTIFF'S OPPOSITION FAILS TO ADDRESS THE COMPLAINT'S DEFICIENCIES**

The critical deficiencies in Plaintiff's Complaint, unanswered in her opposition, render the Complaint insufficient under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, \_\_\_ U.S. \_\_\_, 129 S. Ct. 1937 (2009).

1        First, Plaintiff's opposition does not address the Complaint's failure to link its few  
2        factual allegations to this Plaintiff, to her prescription for Plavix®, or to her alleged  
3        injuries. Plaintiff does not explain how the FDA warning letters cited in the Complaint  
4        are relevant when she never alleges that that she or her prescribing doctors ever saw or  
5        relied on the promotional materials at issue. *See* Mot. to Dismiss at 4. Plaintiff does not  
6        explain how the two studies cited in the Complaint relate to this Plaintiff, since the  
7        Complaint nowhere alleges that Plaintiff would fall into one of the groups of patients  
8        studied. *See id.* at 4-5. The scant facts alleged are therefore irrelevant to Plaintiff's  
9        claims and cannot serve as a basis for liability.

10       Second, Plaintiff's opposition nowhere addresses the Complaint's failure to plead  
11       essential elements of her claims. Plaintiff does not contest that binding Ninth Circuit  
12       precedent requires a complaint to "allege sufficient facts to state the elements of [the  
13       relevant] claim." *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1122 (9th Cir.  
14       2008) (cited in Mot. to Dismiss at 7-8). Nor does Plaintiff directly address the  
15       Complaint's failure to plead factual allegations supporting at least one essential element of  
16       every claim she pleads. For example, Plaintiff's opposition fails to address the following  
17       deficiencies in the Complaint:

- 18       • Plaintiff's Complaint alleges failure to warn, but does not explain what was  
19       allegedly wrong with the FDA-approved Plavix® product labeling and  
20       ignores the warnings that were included in the Plavix® package insert,  
21       which specifically described the bleeding risk associated with Plavix®. *See*  
22       Mot. to Dismiss at 9.
- 23       • Plaintiff's Complaint does not allege what warning should have been given,  
24       or that Plaintiff's physician would not have prescribed Plavix® had he or  
25       she received such a warning. *See id.* at 9-10.<sup>1</sup>

26       <sup>1</sup> Defendants concede that the Complaint did name Plaintiff's prescribing physician.  
27       *See* Comp. ¶ 31; Mot. to Dismiss at 10; Opp'n at 12 n.6. But merely naming the doctor  
28       does not help Plaintiff overcome the pleading failures that Defendants identified. Plaintiff  
     nowhere alleges what risk information her physician supposedly lacked, what alleged  
     misrepresentations supposedly influenced the doctor's prescription, or whether an

- 1 • Plaintiff alleges design defect, but the Complaint does not say what about
- 2 Plavix®'s design was allegedly defective. *See id.* at 10-11.
- 3 • Plaintiff's Complaint does not allege facts that could fulfill either the
- 4 "risk/utility" test or the consumer expectation test for design defect. *See id.*
- 5 at 11.
- 6 • Plaintiff asserts an emotional distress claim, but the Complaint does not
- 7 point to any "outrageous" conduct or explain what severe emotional distress
- 8 Plaintiff allegedly suffered. *See id.* at 12.
- 9 • Plaintiff asserts a fraud claim, but pleads no facts showing any connection
- 10 between Defendants' purportedly deceptive marketing practices and
- 11 Plaintiff's Plavix® prescription. *See id.* at 14-15.
- 12 • Plaintiff's Complaint never identifies any express warranty that Defendants
- 13 allegedly made, nor does it make any suggestion as to what or how a
- 14 bargain was struck between Plaintiff and Defendants. *See id.* at 16.

15 Without facts to support all of the required elements of any of her legal theories, Plaintiff  
 16 does not state a claim for relief against Defendants.

17 Third, the Court should reject Plaintiff's attempt to recast the Complaint's  
 18 conclusory allegations as facts. *See Opp'n* at 10-11. The bullet-point list that Plaintiff  
 19 claims to be factual allegations of wrongdoing by Defendants consists of one content-less  
 20 allegation after another. *See id.* For example, Plaintiff claims that Defendants "[f]ailed to  
 21 fully, truthfully, and accurately communicate the safety and efficacy of Plavix and

22  
 23 alternative warning would have changed the physician's prescribing behavior. *See Mot.*  
 24 to Dismiss at 10.

25 Contrary to Plaintiff's accusation, Defendants did not claim that the New Jersey  
 26 district court dismissed the entirety of the complaints before it. *See Opp'n* at 12 n.6; *Mot.*  
 27 to Dismiss at 5 ("The New Jersey plaintiffs geared their allegations toward consumer  
 28 fraud and negligent misrepresentation claims, and the New Jersey Court granted  
 Defendants' motion to dismiss those claims."). In any event, the New Jersey court did not  
 dismiss the entirety of the complaints in those cases because Defendants did not seek  
 dismissal of all claims at that time. That the New Jersey court allowed claims to proceed  
 when no party moved to dismiss them does not support Plaintiff's opposition to the  
 motion here.

intentionally and fraudulently mislead [*sic*] Plaintiff about the risks associated with Plavix.” *Id.* at 10. Under *Twombly* and *Iqbal*, such “labels and conclusions” and “naked assertions devoid of further factual enhancement” are insufficient and not entitled to the assumption of truth. *See Iqbal*, 129 S. Ct. at 1949; *see also, e.g., Lewis v. Abbott Labs.*, No. 08 Civ. 7480, 2009 WL 2231701, at \*4 (S.D.N.Y. July 24, 2009) (describing as “conclusory” and disregarding the plaintiff’s allegations that the drug at issue was “inherently dangerous” and that “its side effects outweigh its benefits”). Plaintiff’s Complaint consists almost entirely of exactly the type of conclusory pleading that must be ignored under *Twombly* and *Iqbal*.

## II. PLAINTIFF’S ATTEMPTS TO MINIMIZE *TWOMBLY* AND *IQBAL* ARE WITHOUT MERIT

Plaintiff’s opposition argues that *Twombly* and *Iqbal* did not alter the existing pleading standard, but ignores Ninth Circuit precedent recognizing that those cases do change the law governing sufficiency of a complaint. In *Moss v. U.S. Secret Service*, 572 F.3d 962, 972 (9th Cir. 2009), the Court of Appeals explained that “[u]nder the Court’s latest pleadings cases . . . the facts alleged in a complaint must state a claim that is plausible on its face. As many have noted, ***this is a significant change, with broad-reaching implications.***” (emphasis added) (cited in Mot. to Dismiss at 7). Plaintiff supports her argument that *Twombly* and *Iqbal* did not really change the pleading rules only by citation to a case from another circuit and case law that predate *Twombly* and *Iqbal*.<sup>2</sup> *See* Opp’n 8-10.

Plaintiff’s argument that *Twombly* and *Iqbal* do not apply to a personal injury case

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<sup>2</sup> Plaintiff quotes at length from a Seventh Circuit opinion by Judge Posner soon after *Iqbal* was handed down to suggest that that “*Twombly/Iqbal* does not mandate a widespread change in pleading standards.” Opp’n at 8-9 (quoting *Smith v. Duffey*, 576 F.3d 336, 340 (7th Cir. 2009)). Putting aside that Seventh Circuit law does not govern here, Plaintiff ignores that Judge Posner ultimately dismissed the complaint in *Duffey*. Moreover, Judge Posner acknowledged more recently that “the Supreme Court’s new approach . . . requires the plaintiff to conduct a more extensive precomplaint investigation than used to be required and so creates greater symmetry between the plaintiff’s and the defendant’s litigation costs, and by doing so reduces the scope for extortionate discovery.” *Swanson v. Citibank, N.A.*, 614 F.3d 400, 412 (7th Cir. 2010) (Posner, J., dissenting).

such as this is also wrong.<sup>3</sup> See Opp’n at 10. The Supreme Court expressly held that the pleading requirements of *Twombly* and *Iqbal* apply to all civil actions, without regard to the particular facts or cause of action alleged. See *Iqbal*, 129 S. Ct. at 1953 (“Our decision in *Twombly* expounded the pleading standard for ‘all civil actions.’”) (citing Fed. R. Civ. P. 1). The Ninth Circuit has expressly recognized this holding. See *Moss*, 572 F.3d at 969 n.7 (“[T]he *Iqbal* Court made clear that *Twombly*’s ‘plausibility standard’ applies to pleadings in civil actions generally . . . .”); *William O. Gilley Enters., Inc. v. Atl. Richfield Co.*, 588 F.3d 659, 667 (9th Cir. 2009) (“[W]e have held that *Ashcroft v. Iqbal*, \_\_\_ U.S. \_\_\_, 129 S. Ct. 1937, 1953, 173 L.Ed. 2d 868 (2009), makes clear that the pleading requirements stated in *Twombly* apply in all civil cases . . . .”). And numerous district courts have applied *Twombly* and *Iqbal* to products liability claims against pharmaceutical manufacturers. See *Gilmore v. DJO, Inc.*, 663 F. Supp. 2d 856 (D. Ariz. 2009); Mot. to Dismiss at 10 n.11, 11 n.14 & 16 n.17 (citing cases). Plaintiff does not even attempt to address or distinguish the product liability cases cited in Defendants’ motion, nor does she cite any cases that reach a contrary result on facts similar to these.

### III. PLAINTIFF IS NOT ENTITLED TO DISCOVERY TO SEEK TO CURE HER PLEADING FAILURES

Plaintiff’s suggestion that the Court should permit discovery before she should be required to plead adequate facts, see Opp’n at 13-14, has it exactly backwards. Under *Twombly* and *Iqbal*, a plaintiff must meet the threshold pleading requirements before exposing a defendant to the burden and expense of civil discovery. See *Twombly*, 550 U.S. at 557-60 (discussing at length the importance of weeding out deficient complaints

<sup>3</sup> Plaintiff cannot rely on *Swierkiewicz* and *Leatherman* in light of *Twombly*. See Opp’n at 9-10 (citing *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002); *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163 (1993)). As the Supreme Court explained in *Twombly*, *Swierkiewicz* merely rejected a special heightened pleading standard in Title VII cases. See *Twombly*, 550 U.S. at 569-70. *Leatherman*, on which the Court in *Swierkiewicz* relied, similarly rejected a heightened pleading standard for municipal liability claims brought under 42 U.S.C. § 1983. See *Swierkiewicz*, 534 U.S. at 512-13; *Leatherman*, 507 U.S. at 168-69. To the extent that these cases ever embraced a more forgiving pleading standard than announced in *Twombly*, they are no longer good law. See *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009); *Francis v. Giacomelli*, 588 F.3d 186, 192 n.1 (4th Cir. 2009).

1 prior to burdensome discovery); *Iqbal*, 129 S. Ct. at 1950 (Rule 8 “does not unlock the  
2 doors of discovery for a plaintiff armed with nothing more than conclusions.”); *see also*  
3 *Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 792, 796 (S.D. Ohio 2009)  
4 (granting a motion to dismiss under *Twombly* notwithstanding plaintiffs’ argument that  
5 discovery was necessary before they could adequately allege that a pharmaceutical drug  
6 contained a defective design).

7 Plaintiff’s argument that drug product liability claims cannot be pleaded in any  
8 more detail without discovery is simply wrong. For example, the Plavix® label -- the key  
9 source of product warnings in a prescription drug case -- is publicly available. Plaintiff  
10 has ample access to facts relevant to design defect, such as hundreds of clinical studies on  
11 Plavix® that are publicly available, including through websites such as  
12 <http://clinicaltrials.gov/>. Plaintiff has access to her own treating physician to investigate  
13 facts concerning the learned intermediary doctrine and any alleged misrepresentations  
14 made to the doctor. *See Begley v. Bristol-Myers Squibb Co.*, Civil Action No. 06-6051  
15 (FLW), 2009 WL 5216967, at \*10 (D.N.J. Dec. 30, 2009) (“[T]hese factual allegations are  
16 not of the type of facts that are within the control of, and therefore subject to concealment  
17 by Defendants. Instead, these important details regarding misrepresentations made to, and  
18 relied upon by, Plaintiffs and their physicians are within Plaintiffs’ ken, but are nowhere  
19 to be found [in the complaints].”). Nothing prevented Plaintiff from conducting  
20 elementary fact investigation before filing a lawsuit.

#### 21 **IV. THE COURT HAS DISCRETION TO DISMISS THE COMPLAINT WITH** 22 **PREJUDICE AND DENY LEAVE TO AMEND**

23 The Court may dismiss Plaintiff’s Complaint with prejudice if it believes such a  
24 result is appropriate. Whether to grant or deny leave to amend a complaint is within the  
25 Court’s discretion. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1372 (Fed.  
26 Cir. 2008) (“A district court generally enjoys broad discretion when assessing the  
27 propriety of a motion to amend.”) (citing *Chappel v. Lab. Corp. of Am.*, 232 F.3d 719, 725  
28 (9th Cir. 2000)).



Futility of amendment is a valid basis to deny leave to amend. *Ventress v. Japan Airlines*, 603 F.3d 676, 680 (9th Cir. 2010); *see also Allen v. City of Beverly Hills*, 911 F.2d 367, 374 (9th Cir. 1990) (affirming denial of leave to amend when it did not appear that the plaintiff could state a claim). Here, Plaintiff could have explained what facts she sought to re-plead and how they would comprise a legally sustainable case. Plaintiff could have included a proposed amended complaint as required by Local Civil Rule 15.1 for motions to amend. *See Walraven v. Everson*, No. CV 06-0864-PHX-FJM, 2007 WL 1893645, at \*1 (D. Ariz. July 2, 2007) (denying leave to amend because “[w]ithout the proposed amended complaint, we are unable to determine in what respect it differs from plaintiff’s original pleading, and cannot assess the merits of defendant’s opposition to plaintiff’s request”). Plaintiff has done neither. In these circumstances, the Court would be justified in exercising its discretion to dismiss the Complaint with prejudice. *See Frey*, 642 F. Supp. 2d at 796 (denying request in the alternative for leave to amend design defect allegations because the plaintiffs had not shown that they could allege facts that would state plausible claims for relief under *Twombly*).

### CONCLUSION

For all the reasons stated herein and in Defendants’ opening brief, the Court should grant the Motion to Dismiss.

DATED this 7th day of July, 2011.

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 7th day of July, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record:

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